3962. Misbranding of "Bad-Em Salz." U. S. * * * v. The American Laboratories, a corporation. Tried to the court and jury. Verdict of guilty. Fine, $100. (F. & D. No. 5862. I. S. No. 1659-e.)

On December 3, 1914, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for said district, and on March 17, 1915, an amended information, against The American Laboratories, a corporation, organized under the laws of the State of South Dakota, and having a place of business at Philadelphia, Pa., alleging shipment by said company, in violation of the Food and Drugs Act, as amended, on or about November 27, 1912, from the State of Pennsylvania into the State of New York, of a quantity of "Bad-Em Salz" which was misbranded.

The product was labeled: (On bottle) "This Powder reproduces the medical properties of the great European Springs, famous for centuries for the cure of diseases of the stomach, intestines, liver, kidneys and bladder. Bad-Em Salz cleanses the digestive tract, promotes the flow of bile, dissolves gall stones and gravel in the kidneys or bladder, and frees the blood of poisonous impurities. Bad-Em Salz is free from Acetanilid, Bromides, and all other dangerous narcotics. Guaranteed by the American Laboratories under the Food and Drugs Act, June 30, 1906. Serial No. 29210 Bad-Em Salz Caution Always use a dry spoon and never leave the bottle open Directions * * * Price 25 cents The American Laboratories Philadelphia, U. S. A." (Blown on bottle) "Bad-Em Salz." (On wrapper) "29210 Guaranteed under the Food and Drugs Act, June 30, 1906. Bad-Em Salz. This powder represents the medicinal agents obtained by evaporating the water from the famous European Springs. The experience of a thousand years confirmed and approved by every important modern medical authority, demonstrates it to afford an incomparable remedy for Diseases of Stomach, Intestines, Liver, Kidneys and Bladder Cleansing the Digestive Tract Promoting the Flow of Bile Neutralizing Uric Acid Dissolving Gall Stones and Gravel in the Kidneys or Bladder and Freeing the Blood of Poisonous Impurities Price, 25 cents. Prepared Exclusively by the American Laboratories Philadelphia, U. S. A."

The pamphlet or circular accompanying the product contained, among other things, the following: "Bad-Em Salz stimulates the liver to throw off more bile, carrying away poisons and dissolving gall stones.

"Gastritis and Catarrh of the Stomach (Inflammation of the Stomach) are usually due to drinking and eating too much and can be 'headed off' by a large dose of Bad-Em Salz at bed time and again the next morning.

"Diabetes, the disease characterized by sugar in the urine, is accompanied by great hunger, thirst and weakness. It is particularly prone to attack fat people, and like Obesity itself, yields to diet and Bad-Em Salz.

"A dose of Bad-Em Salz every morning will make you well and keep you well.

"Gall Stones are much more common than is generally known. One woman in every six has them, though often she doesn't suspect it. Mild early symptoms, such as indigestion, heartburn, nausea, jaundice, bilious attacks, etc., should be treated at once, without waiting for the agonizing pain of gall stones colic to develop. Begin at once to take Bad-Em Salz, a teaspoonful or more, better in hot water, three times a day. This must be kept up for weeks, but it leads to recovery without the terrible suffering and danger of a surgical operation.

"Chronic Inflammation of the Kidneys (Bright's Disease) is frequently due to Uric Acid. Rest, a simple diet of milk and fresh vegetables with little meat and small doses of Bad-Em Salz at bedtime and on arising will prevent or check the disease.

"Catarrh of the Bladder can be quickly relieved by one or two glassfuls of water containing Bad-Em Salz on arising in the morning, repeated, if necessary, several times during the day."

Analysis of a sample of the product by the Bureau of Chemistry of this department showed the following results:

Sodium chlorid (per cent)	12.45
Sodium sulphate (per cent)	39.40
Sodium bicarbonate (per cent)	39.96
Tartaric acid (per cent)	2.33

The sample consists of common salt (sodium chlorid), Glauber salt (sodium sulphate), baking soda (sodium bicarbonate), and a small amount of tartaric acid.

Misbranding of the product was alleged in the information for the reason that the following statements appearing in the label on the package aforesaid, to wit: (Bottle) "This Powder reproduces the medical properties of the great European Springs, famous for centuries for the cure of diseases of the stomach, intestines, liver, kidneys, or bladder." (On wrapper around bottle) "This Powder represents the medicinal agents obtained by evaporating the water fro mthe famous European Springs", were false and misleading in that they indicated to the purchasers thereof, and created in the minds of the purchasers thereof, the impression and belief that said article reproduced the medical properties of the great European springs, famous for centuries for the cure of diseases of the stomach, intestines, liver, kidneys, or bladder, and that it represented the medicinal agents obtained by evaporating the water from the famous European springs, when, in truth and in fact, said article did not reproduce the medical properties of the great European springs, famous for centuries for the cure of diseases of the stomach, intestines, liver, kidneys, or bladder, and did not represent the medicinal agents obtained by evaporating the water from the famous European springs.

Misbranding was alleged for the further reason that the statement on the label aforesaid, to wit, "Bad-Em Salz", was false and misleading in that it indicated that said preparation was composed of substances or salts derived from the waters of the springs at Ems, Germany, whereas, in truth and in fact, said preparation was not composed of salts or substances derived from the waters of the springs at Ems, Germany, but was an artificial preparation consisting essentially of common salt, Glauber salts, baking soda, and tartaric acid.

Misbranding was alleged for the further reason that the statement on the label of the bottle aforesaid, to wit, "This Powder reproduces the medical properties of the great European Springs, famous for centuries for the cure of diseases of the stomach, intestines, liver, kidneys, and bladder. Bad-Em Salz * * *", was false and misleading in that it indicated that the said preparation was composed of substances or salts derived from the waters of the springs at Ems, Germany, and that said preparation reproduced the medical properties in substances or salts found in the waters of the springs at Ems, Germany, whereas, in truth and in fact, said preparation was not composed of substances or salts derived from the waters of the springs at Ems, Germany, and did not reproduce the medical properties of the substances or salts found in the waters of the springs at Ems, Germany.

Misbranding was alleged for the further reason that the following statement regarding the therapeutic or curative effects of the article appearing on the label of the bottle aforesaid, to wit, "Bad-Em Salz . . . dissolves Gall Stones and Gravel in the kidneys or bladder . . .", was false and fraudulent in that the same was applied to said article knowingly and in reckless and wanton disregard of its truth or falsity so as to represent falsely and fraudulently to the purchasers thereof, and create in the minds of purchasers thereof, the impression and belief that it was, in whole or in part, composed of, or contained, ingredients or medicinal agents effective for dissolving gallstones and gravel in the kidneys or bladder, when, in truth and in fact, said article was not, in whole or in part, composed of, and did not contain, ingredients or medicinal agents effective for dissolving gallstones and gravel in the kidneys or bladder.

Misbranding was alleged for the further reason that the following statements regarding the therapeutic or curative effects of said article, included in the circular or pamphlet aforesaid, to wit, "Bad-Em Salz * * * Dissolving Gall Stones. Gastritis * * * can be 'headed off' by a dose of Bad-Em Salz at bedtime and again the next morning. Diabetes * * * yields to diet and Bad-Em Salz. Gall Stones * * * Take Bad-Em Salz. It leads to recovery. Chronic Inflammation of the Kidneys * * * Bad-Em Salz at bedtime and on arising will prevent or check the disease. Catarrh of the Bladder can be quickly relieved by one or two glasses of water containing Bad-Em Salz * * *," were false and fraudulent in that by means of the said circular or pamphlet they were applied to said article knowingly and in reckless and wanton disregard of their truth or falsity, so as to represent falsely and fraudulently to purchasers thereof and create in minds of purchasers thereof the impression and belief that said article was, in whole or in part, composed of, or contained, ingredients or medicinal agents effective, among other things, for dissolving gallstones and effective for the prevention of gastritis, and effective for curing diabetes and effective for preventing or checking chronic inflammation of the kidneys, and effective for relieving catarrh of the bladder, when, in truth and in fact, said article was not, in whole or in part, composed of, and did not contain, any ingredients or medicinal agents effective, among other things, for dissolving gallstones or effective for the prevention of gastritis, or effective for curing of diabetes, or effective for preventing or checking chronic inflammation of the kidneys, or effective for relieving catarrh of the bladder.

On March 12, 1915, the defendant filed its motion to quash the second count of the information for the reason and because:

The amendment of August 23, 1912 (37 Statutes at Large, 416), to the Food and Drugs Act upon which amendment said second count is based, is contrary to the Constitution of the United States of America and void, in that—

1. Said amendment attempts to establish criteria in matters of opinion which are incapable of judicial ascertainment and decision, and is not a regulation of commerce.

2. It attempts, beyond what would amount to a reasonable and proper regulation, to restrict and circumscribe the citizen's right to engage in commerce.

3. Said amendment in effect deprives persons of property without due process of law.

On March 31, 1915, the court entered a formal order overruling and refusing said motion to quash.

On April 7, 1915, the case came on for trial before the court and a jury, and after the submission of evidence and arguments by counsel, the following charge was delivered to the jury by the court (Dickinson, *J.*):

GENTLEMEN OF THE JURY: The facts of this case have been so fully discussed by counsel, and the points in controversy have been so clearly and adequately presented to you, that I do not feel called upon to take up much of your time in reference to the facts. It has been suggested that I say something to you with respect to your attitude, as a jury, toward the trial of cases, not merely of this kind but of all kinds of cases, on this side of the court; and it has always seemed to me that that is a helpful thing to any man, or body of men, who are called upon to decide any question, to get clearly in their minds what their proper attitude toward the questions which are presented to them is.

Now, we are all accustomed, indeed proud, to say that this country of ours is a self-governed country, meaning by that that the people here govern themselves. We do not select any men for any reason of supposed superior intelligence, or experience, or training, or birth, or anything of that extraneous character to govern us, but we think, at least, and we like to feel, that we govern ourselves. Now a very important function of government is the decision of cases, the trial and determination of disputes between citizens. In cases of this kind, on what is called the criminal side of the court, we have this fact, which I would like to emphasize and impress upon your minds: If a cause is to be decided, it necessarily follows that some one or some number of persons must decide it. That is perfectly clear, and under our system of law and of govern-

ment the tribunal which is to decide questions of this kind is a jury, just such a jury as you twelve men constitute; and the people of this country have time and again shown, not only a decided preference, but a most emphatic insistence, that no man shall be found guilty of an infraction of the criminal law until his guilt has first been passed upon by a jury. Now that, therefore, involves that what the people of this country expect of you, and therefore what the law requires of you, is that your verdict shall be the reflection of your own judgment, your judgment as a jury, and that means that you are not to accept the opinions or the judgment of somebody else. It is your judgment which is to govern and nobody else's. Of course, that does not mean that when counsel address you in the course of the argument of the case you are to pay no attention to the arguments which counsel address to you. You are to listen to them; you are to consider them; you are to weigh them; you are to estimate their strength, or detect their weaknesses if there be weaknesses in the argument. You are to give all that is said to you by counsel a due and proper consideration; but you are to pass it through the sieve of your own judgment, so that, when you reach a conclusion, it is your conclusion and your judgment which is registered by your verdict, and you do not slavishly accept the opinion of counsel or anybody else.

Now, what applies to counsel applies just as well to the trial judge, and if, in the course of what I may say to you about the facts of this case, I should unintentionally—and if it was done it would be unintentionally—let slip an expression of opinion, you are not to regard that as having any weight upon you at all, other than the facts or the argument upon which it is based show that it should have. You are not to accept the views of the trial judge, any more than the views of anyone else. I want to say to you that I not only have no intention of expressing an opinion, but that I have no opinion to express; so that, if you should get the idea that the trial judge, for instance, had a certain opinion about this case, it would be a mere guess upon your part, and you would be just as likely to guess wrong as guess right, for there is just one chance out of two of your being right. So that you come back every time to your own opinion about it. Now that is the case with respect to the opinion of anybody else. If somebody in this courtroom had expressed an opinion, or the same man, or somebody else, had put that opinion in print and it had appeared in a newspaper or magazine article, or anything of that kind, you are not to pay the slightest regard or attention to those opinions. In the first place you can take it for granted, almost without exception, that the man has no knowledge upon which he bases his opinion anyhow. It is your opinion which is to govern, and that opinion, or that judgment, or that verdict—for they all mean substantially the same thing—is based upon, is a deduction from, the facts in the case as they appear, and they can appear only in one way, and that is from the evidence, of which the sworn testimony in the cause is a part; so that you are to take your facts from the witness box, and you are to use your judgment in reasoning upon those facts to the conclusions which you may reach.

Now, the law in the trial of cases lays down certain rules. They are, if I may be permitted to use a colloquial expression, the "rules of the game," and you are to follow those rules. One of the things is, as I have said, and I repeat it, so that you may get into the proper attitude of mind toward the decision of this case, that you are here as the representatives of the Government of this country, precisely in an analogous sense to that in which our Representatives in Congress and Senators are representatives, in the sense in which the President, the heads of departments, and all the other members of the executive department of the Government are representatives of that Government of the people. Now our Representatives in Congress pass laws. Our other representatives, the juries of the land, apply and enforce those laws. Of course, you can see at once that it is idle for some of the Representatives of the people in Congress to pass laws if the other representatives of the people, the juries of the land, either through indifference or for any other cause, refuse to apply, and in that sense to enforce, the laws. Now, one of the rules of the game is that you also, in the sense of representing justice, represent the defendants in the case. I do not mean by that that you represent them in the sense in which their counsel represents them; but, in representing justice you necessarily must stand for the rights of the defendants, and the law gives them certain rights. Now, just as I said about the law, that it is idle to have a law unless it is enforced, so it is idle for the people, through their laws or through their constitutions, to say that defendants shall have certain rights, unless juries, when cases come up, apply that law by according to defendants those rights, and they ought to be accorded them fully and freely and ungrudgingly.

Now, one of the rights of every defendant is what is called the presumption of innocence. You are all familiar with that principle of law, and it is unnecessary for me to dwell upon it. I will let it go with the passing observation that, in substance, it means this: That the question of the guilt of a man is not to be a thing taken for granted, or assumed, or jumped at, or guessed at, or reached out of prejudice from one

cause or another, but it must be a reasoned result. The man is in law innocent until he is proven guilty, and he is proven guilty by facts being brought to the attention of the jury in the proper way, from the witness box, and then the jury, applying the law to those facts and using their judgment and their reason, reach the conclusion that he is guilty; and under the law no man can be found guilty without that procedure.

Another right of the defendant with which juries are also familiar is what is known as the doctrine of reasonable doubt, and that is to say, the law says to the prosecution in every case, "You have accused this man of crime. Now prove it." That is the first proposition; and, secondly, "Remember that in proving it you are to prove it beyond a reasonable doubt." It is, therefore, important that the jury get into their minds, as nearly as they can, exactly what the law means by this doctrine of reasonable doubt. You will notice that the doctrine is not a doubt, but a reasonable doubt. In general terms, it means such an uncertainty as to the proper conclusion to be reached that a normal, sensible man finds himself unable to reach a conscientious conclusion without such a degree of hesitation as renders the conclusion which he might reach doubtful. Now, it is a reasonable doubt in another sense. It is no mere speculative, theoretical doubt. For instance, in some cases the only kind of proof that can be found is the proof that is built upon deductions that arise from a fact here and a fact there and another fact in some other place, or what is called circumstantial evidence. Now, some people have a general, what you might call speculative, theoretical doubt about the value of all kinds of circumstantial evidence. But you are not to be influenced by a doubt of that kind. Or, as it has been often expressed, it is a reasonable doubt, such a doubt as that, when the mind of a normal, reasonable man is following step by step along the path of reason, it encounters an obstacle, in the form of an honest doubt, which, in spite of the best effort of all his reasoning powers, he is unable to surmount or get around, or remove that obstacle, then the law says to him, "Stop; you need go no farther. The defendant is entitled to the benefit of that doubt, and on that ground you should acquit." But it is no mere whim of disbelief or unbelief.

Now, that is rather a long prelude to this case. Another good way to approach the consideration of the case is to get firmly in your mind what the case is that you are asked to decide, and therefore a very reasonable question for you to ask yourselves and settle in your minds is, What is the charge against this defendant, upon his guilt or innocence of which we are asked to pronounce? Now, the charge arises generally under what are called the Pure Food and Drug Acts, the general purpose of which you will all understand, and I am sure that you will appreciate the value and the general beneficence of laws of that kind. They have a very proper purpose, and, like every other law, if they have been broken, there should be no hesitancy in the enforcement of the law; and particularly I may call attention to laws of this character, for this very obvious reason: If we have no laws of this kind and men may put out whatever they please and say about it whatever they please, men who are approached to purchase these things, knowing that the door is wide open for any degree of deception, are put upon their guard and they are in a position to protect themselves, so far as they can, by the exercise of their own judgment and by any investigation which they can make for themselves. But if we have laws of this kind you can see that there would naturally grow up, after while, a disposition to rely upon the law, and, if the law requires that certain things be done and certain other things be not done, we easily get into the way of taking it for granted that those things have been done which should have been done, and that those things have not been done which ought to be omitted. In other words, we get to relying upon the law and we relax the efforts for our own protection.

Now, while all of that is true, and your attitude toward the enforcement of the law should be precisely that attitude, you are not to forget that in each particular case the question before you is not whether the law should be enforced, because that goes really without saying, but the question is has the particular defendant before you been guilty of an infraction of that law, and the real question you have to decide is the guilt of the defendant beyond the reasonable doubt which I have defined, under the evidence and sworn testimony in the case.

Now, your attention has been called to what we might term two laws on this subject. One, which was the original law, is aimed at the misbranding of articles. We may confine it to drugs in this case, because we are concerned with drugs here. Now, that merely means, as has been explained to you, that when any one puts out an article he must tell the truth about it. He must state just what it is, and if he has misbranded it in the sense that, in speaking of what it is, he has made false and misleading statements with respect to it, or in common parlance it comes practically to what we would call lied about it as to what it was, its ingredients, its composition, the substance it is, then there is a misbranding under the law. Now, of course, you will understand that, particularly with respect to drugs, a man might not confine himself to that. There are two things that he might do, or either of which he might

do. He may put out a statement as to what the thing is, and then he may put out another statement as to what the thing will do; if it is a drug, what its curative or therapeutic qualities are, what it will help in the way of human ailments or disease, or what, in the common parlance of the street, we might call the "brag" about the article. Now, you see, there is a difference there. One statement refers to what the thing is; the other statement refers to what it will do or accomplish; and the second subject is made the field of operation of what you have heard called the Sherley amendment, which makes it an offense against the law for anyone to make statements which are false or fraudulent with respect to what the drug will accomplish.

Now, you have that distinction, I am sure, clearly in your minds; but let me give it to you by way of a very trite and commonplace illustration. We all know that there are certain waters contained in the flow of springs everywhere throughout the world that have a reputation for the possession of certain curative properties; that they will, if taken into the human system, produce certain results. The number of them is practically limitless. Their reputations vary in width and in degree. How much of their reputation is due to the inherent merits or virtues of the waters themselves, and how much of it is due to the arts of the advertisers, we do not know; but we do know that they have that kind of a reputation. For illustration, a water of which we see very much is what is known as the Vichy water, or Celestin. It is used frequently as a table water. You can get it at your clubs, you can get it at the hotels, and people have a wish to drink it and they do drink it Now, supposing a man in Philadelphia, for instance, would gather together some rain water, or turn the faucet in the hydrant and get some Schuylkill water, and would bottle it and would put it out on the market, and would say that it was Vichy water, or Celestin, or that it was Buffalo lithia water, or any of these other waters that have a reputation. Now, you see, he would be misbranding that. He would be telling a falsehood as to what the thing was. Now, supposing he went farther, it being nothing more than rain water, and he put on there a statement that that would cure diabetes, or that it was a specific for diarrhea, or any other of the common ailments of man. Now, in saying that he would be making a false statement, at least, he might be making one, and, in the instance which I have given, nobody would doubt but what he was making both a false and a fraudulent statement.

Now, that second proposition is the Sherley amendment. In this idea of fraudulent, is involved the thought that he is doing it for the purpose of defrauding people of their money, or something else of value. That idea is involved in it. Now you will notice that that contains two thoughts—the thing must be false and the thing must be fraudulent.

Now, let us go back for just a moment to the first proposition, the misbranding. There are four counts in this indictment which you will have to pass upon. Three of the counts relate to the general subject; that is, 1, 2, and 3 relate to the first proposition which I have attempted to make clear to you, and the fourth count relates to the second proposition. Now, the charge is, in these counts, that there was a misbranding. One of them states a misbranding in this particular, another one states it in another particular, and the third states it in more particulars than one. The essential charge is that the defendant in this case has misbranded these salts, in that the defendant has put them out under a false and misleading statement, and that they are not what these statements would lead anyone to suppose that they are; and one of the propositions is that, in the very name itself that they have built up a name for the purpose of conveying the thought, and in that sense of making the statement, that the salts contained in one of these packages are the salts that are contained in the waters of the springs at or near the city of Ems, in southeastern Germany. Now, the other is that they state that they reproduce, or that they represent, the salts, the ingredients, the properties, that are contained in the waters of the famous European springs, and that those statements are misleading, according to the charge in one indictment, because they convey the statement of the fact, or are misleading in the sense that they tend to produce the impression that they are a reproduction of the very salts, the very ingredients, the very composition, of these well-known medicinal spring waters; and the other is that the very salts contained in this package are salts that are obtained by the process of taking the actual spring water and evaporating it, and these very salts are the residuum which is thus obtained. Now, the United States has produced before you evidence, as to which apparently there is not any controversy, that these packages do not contain any such thing. That really is not the dispute in this case. The defense is that there is no such statement upon these packages; that that is not what is said nor what is intended; and that there is no justification for the assertion made by the United States that any such misleading statement is made; that all that is intended is that they reproduce and that they represent, in the sense that these salts contain, in their ingredients, the essential properties, qualities, the ability to produce effects, which the waters have. In

other words, they are a representation in the sense in which it can be said—has indeed been said in this case—that counsel represent a client, or in which a member of Congress represents his constituents, that he is there acting in place of and in lieu of. Now, that is the essential point which you are to pass upon as to the first three counts of this indictment. I might say as an illustration (you all saw it in the papers, and it has just occurred to me as an illustration of what I mean) that somebody was found down, I think, in south Jersey, selling sawdust, accompanied with the statement that it had been taken from the Sunday Tabernacle in Philadelphia, while in point of fact, of course, it had been taken from the nearest sawmill. That represents, in the rough, and as a trite illustration, just exactly the point of the distinction around which the real controversy in this case turns as to these first counts.

Mr. OLIVER. Would your honor just explain a little further about the sawdust proposition? I think it might convey the impression that our proposition was like the sawdust proposition.

The COURT. Oh, I am sure the jury does not understand it in that way. I meant they are alike in this sense: Anybody who wants to, who has a fancy, who has a sentiment, as we can understand many people might have, and, therefore, would value the possession of something that was a memento and reminder of the tabernacle meetings, might like to have even some of the very sawdust from the sawdust trail, and, if he fancies it, he has a perfect right to have it and any man has a perfect right to sell it to him; but you would all recognize the difference between a man who actually went to the tabernacle and gathered the sawdust which was the real sawdust of the tabernacle and sold it to the man as the sawdust of the tabernacle, and the man who went to the nearest and most convenient sawmill and got some other sawdust and put that off on the man as if it had been gathered in the other place. Now, that is essentially the charge which the United States is making against the defendant here, that they represented that as the actual, real sawdust. The defense is that they did not make any such representation at all; that they never said that this was the salt actually taken from the real springs, but that they had a salt which reproduced and represented that salt in all its essential elements. That is, I think, quite sufficient to be said upon that point.

Now, we come to the next point, and that is what I have called the "brag" of the statement—what the thing will do. You can all see that that possesses, or at least suggests, the idea of prophecy. What a thing will do is in the future and in that sense more or less prophetic; but the prophecy is based upon knowledge, and knowledge gained by human experience. Now, it is made an offense under the law for anyone to put out a false and fraudulent statement as to what a medicine will do, in the sense of what it will cure. Take the first illustration that I gave you, a man who was selling nothing more than rain water, and was putting it out under the statement that it would cure rheumatism or cure tuberculosis, and who sold it and obtained money from people by doing that. I do not think it would be straining anybody's conscience to find that that man was making a false and fraudulent statement and to convict him of it, because it would be perfectly clear that he was making it with the purpose and intent of defrauding people of their money; in other words, getting something for nothing. Now there is that idea of intent involved in this fourth count which is not in the other counts. The other counts are a question of fact. There is no intent in it. The question is, Were the things misbranded? This question of fraud involves the idea of the intent. Was there this fraudulent feature in it in that sense? There, gentlemen of the jury, you will have to use your common sense, and the appeal is to your common sense. We can all understand that about many things there is a field for the exercise of difference of opinion; but alongside of it, and at some point approaching and meeting it, is another field—the field of fraud. Now, fraud is a word that nobody can define. Nobody can tell you in words what the word "fraud" means. It belongs to that same category as the word "life" in physiology and in philosophy, or the word "money" in monetary science or in politico economics. Nobody can give a definition of what life is without settling all the theories that cluster around human existence. Nobody can give you a definition of money without settling all the theories of politico economics. And so it is with the word "fraud." And yet it is an idea which the average mind clearly grasps and firmly holds. We know when we are justified in saying "That thing is a fraud," or "That man is a fraud," and it conveys to our mind a very clear and very definite impression. Now, you must have the two things—however, as I said, the thing must be false and it must be fraudulent. The statement which is averred by the United States to be false and fraudulent is essentially the statement that the effect of taking this medicine is that gallstones will be dissolved in the human body. The first thing is, is that true, and you are to determine that if it is a fact. It belongs to the category of what, in one sense, you might correctly phrase as a scientific fact, and you are to determine it, therefore, according to the information that is given to you by the science of medi-

cine—a fact which is to be determined by evidence that comes to you from sources of that kind. Now, will this dissolve gallstones? You have heard the testimony and you can pass upon that question.

The next question is, whether it will or whether it will not. Were these statements made, not as the expression of an honest opinion, or an honest expectation, or an honest belief, with the medicine so made for that purpose, or were they put out for the mere purpose of inducing people, without any basis of real belief, and put out for the purpose of extracting people's money from them without giving them in exchange anything of real value? It is very much akin to the idea of obtaining money by false pretenses, putting the statement out, knowing that there was no foundation for it, having no real expectation or belief that it would have or produce any such result, and doing that for the purpose of fraudulently extracting money from people.

Now, gentlemen, I have taken up twice as much of your time as I had any thought of doing, and I want in closing to put the case to you as one which calls for the exercise of the intelligent, level-headed, common-sense judgment, which I am sure you will apply to it. I ought to say in this connection that it is not necessary for the United States to show that every one of these statements which they have charged to be false is false. It is not necessary for them to show that this article has been misbranded in every particular in which they charge that it has been misbranded. If it has been misbranded as to one particular, or if the statement with respect to the curative properties is false and fraudulent in one particular, then the defendant is guilty as to that statement.

The defendant has asked me to say to you—

"(1) As the offense charged is a misdemeanor, the Government must satisfy you of defendant's guilt beyond a reasonable doubt or you must find for the defendant. All doubts in your minds must be resolved in favor of the defendant."

I affirm that proposition to the extent to which I have already explained to you. It is not that all doubts be resolved in favor of the defendant. It is the reasonable doubt, and the kind of reasonable doubt which I have explained to you.

"(2) The first count in this case does not come within that portion of the act dealing with statements of curative or therapeutic effects of medical preparations. Therefore in deciding whether or not the defendant is guilty you have to determine merely whether the article 'reproduced' the medical properties of the great European springs and 'represented' the medicinal agents obtained by evaporating the water from those springs, or whether those claims made by the defendant were false and misleading."

That I affirm. It is in the line of what I have already explained to you—the distinction between counts 1, 2, and 3, and count 4.

"(3) In reaching a determination of that question you may take into consideration the fact that the National Formulary, which has been adopted as its standard by the United States Government, contains a formula for effervescent artificial Carlsbad salts, and states that so many grains of that salt, when dissolved in so many ounces of water, *represent* an equal volume of Carlsbad water."

I affirm that point. You may take that into consideration, as you may—and indeed should—take into consideration all the facts and circumstances of the case.

"(4) The second count covers the name 'Bad-Em-Salz,' the Government claiming that this name indicated that the preparation is composed of substances derived from the springs at Ems, Germany. In deciding this question you may consider the name in connection with its context; you may take into consideration such facts as that the label states that the preparation merely *represents* and *reproduces* the medicinal agents and properties obtained by evaporation of the water from the famous European springs, and that the label contains at the bottom the words 'The American Laboratories, Philadelphia, U. S. A.' You may also consider whether the springs at Ems are sufficiently known in this country to make the name Bad-Em-Salz misleading, also whether or not the salts from the springs at Ems are known as Bad-Ems Salz, and you may likewise consider such other evidence as may bear on this matter. If under the evidence you do not believe beyond a reasonable doubt that the label indicated that the preparation was composed of substances actually derived from the springs at Ems, you must find for defendant on the second count."

Gentlemen, I affirm that point, that all of the things enumerated there you are to consider, as I have said several times, in connection with all the evidence in the case.

"(5) The third count covers the use of the name 'Bad-Em-Salz' immediately following the phrase, 'This powder reproduces the medical properties of the great European springs, famous for centuries for the cure of diseases of the stomach, intestines, liver, kidneys, and bladder,' the Government claiming that this indicated that the preparation was composed of substances derived from the waters of the springs at Ems and that the preparation reproduced the medical properties of the substances found in

those waters. It is for you to decide, after weighing all the testimony, whether or not the label was false or misleading in the particulars mentioned. If there is a reasonable doubt in your mind, you must find for the defendant."

That is affirmed.

"(6) The fourth count deals with alleged misstatements of the curative effects of this medical preparation. Statements of curative and therapeutic effect, in order to come within the act, as amended, must be statements of fact and not mere expressions of opinion. They must be downright falsehoods, and in no sense expressions of judgment."

I affirm that to the extent that they must be false, and, in addition to that, which is not stated in this point, they must be fraudulent in the sense that I have described.

"(7) A conviction on the fourth count in this case would not be warranted, therefore, unless you are convinced beyond a reasonable doubt that the preparation is absolutely worthless for the accomplishment of the things claimed for it, and is an out and out cheat."

I do not feel justified in accepting the rhetoric employed in the presentation of that point, but I will affirm it to this extent, that, as I have said any number of times, you must be convinced beyond a reasonable doubt that the statement was false and that it was fraudulent in the sense that I have already explained.

The other points are disaffirmed.

The United States has asked me to say to you:

"1. If you believe beyond a reasonable doubt that any one statement as to the curative or remedial properties of this medicine was false in fact, and that the defendant knew that it was false, you may find the defendant guilty on the fourth count."

I make the same answer to that, affirming that to the extent that you must be convinced beyond a reasonable doubt that the statement as to the curative effects was both false and fraudulent.

"2. If you believe beyond a reasonable doubt that this product will not dissolve gallstones in the body, and that the defendant must have known it, you may find the defendant guilty on the fourth count."

I make to that the same answer; as to that specific statement, you must be convinced beyond a reasonable doubt that it was false and also that it was fraudulent.

"3. If you believe beyond a reasonable doubt that this product is worthless for any of the things for which it is labeled, and that the defendant knew this, you may find the defendant guilty on the fourth count."

I will say as to that that you are confined in your deliberations to the statement which is alleged in the fourth count of this information to have been false. You can not travel outside of that to any other statements in the case other than those which the Government itself has alleged to be false and fraudulent. If you find those to be false and fraudulent you may convict, and with that qualification the point is affirmed.

Mr. STERRETT. Or any one of them, your honor.

The COURT. As I have already said to you, the United States is not called upon to prove all of the charge. If they have charged that several of these things are false and fraudulent, and if you are convinced that one of them is, you may convict as to the count which involves that charge.

"4. If you believe beyond a reasonable doubt that any one of the therapeutic claims is absolutely false and was made by the defendant with a careless disregard as to whether it was true or false, you may find the defendant guilty on the fourth count."

That point I disaffirm as phrased. It comes back to the proposition that, if you find the statement is both false and fraudulent, you may convict.

"5. To find the defendant guilty the Government must prove beyond a reasonable doubt that at least one of these therapeutic claims is false and fraudulent. It is not sufficient for the Government to show a mere difference of medical opinion, but if you believe the statement is absolutely false and contrary to scientific fact the mere refusal of some doctors to accept it does not bring a scientific fact into the realm of opinion."

I say as to that, gentlemen, that it is for you to find the proposition as a fact, and I do not accept the qualification in this point of a scientific fact. The opinion of doctors, so far as they testify as experts, is evidence of a fact, just as the testimony of an ordinary witness to a fact within his observation is evidence of the fact. It is for the jury to be convinced of the existence of the fact. The other matters are merely evidence by which the conviction is carried or is not carried to their minds.

"6. If you believe beyond a reasonable doubt that the defendant knew that any one of these therapeutic statements was false and misleading, you may infer a fraudulent intent and find the defendant guilty on the fourth count."

That point I do not affirm to the extent that a mere finding of the falsity is sufficient. The thing may be false and the man may say it, but there must be, before there can be a conviction, the other thought that he says it for the accomplishment of a fraudulent purpose. Both elements must be in the case.

"7. The Government's case must rest upon a basis of fact and not upon a basis of mere opinion, but you may regard a unanimity of scientific opinion as conclusive proof of that scientific fact. By unanimity I mean substantial unanimity, not that perfect consensus of opinion which experience proves to be unattainable. If, for instance, you believe from the evidence that all medical authorities agree that gallstones can not be dissolved within the human body, and that only the charlatans hold a contrary view, that would be unanimity within the meaning of the law. The same thing is true, even if some men honestly hold a contrary view, if you believe that their number is so small as to be negligible, or if you believe they represent that small proportion which can always be found obstinately refusing to accept demonstrated fact. The law does not require the ideal unanimity unobtainable in human society so far as this applies to the fourth count."

I will not affirm that point absolutely with respect to the concrete facts of this case. The evidence is addressed to you. The judgment, the finding, which we are after is your finding of the fact under all of the evidence. None of it is conclusive upon you, none of it is binding upon you, except in so far as it is binding upon your conscience, in that it produces in your minds a conviction of the truth or falsity of a certain fact. If you honestly believe so, beyond a reasonable doubt, then it is binding upon your conscience to say so by your verdict. If the conviction is not carried to your minds I do not care what the opinion or thought of anybody else may be, it is the verdict of you twelve men.

Now, take this case. Do not be afraid to dispose of it because learned doctors have discussed it. That is no reason why you should not take it up to be disposed of by you. Take it up just as you would take up any other problem that confronts you in life. Consider it with the same careful scrutiny, with the same intelligence, the same painstaking care, and the same common sense, and reach a verdict upon these propositions, which are in reality very simple in their statement. There are really, in the rough, two propositions, two charges here: The one is answered by the question, Did this defendant misbrand the contents of these packages, in the sense of making false and misleading statements as to what the contents were? That is one proposition. The other, in the statement of what they would do, or in their curative effects, is any statement which they made false and fraudulent? And so as you answer those questions, so will your verdict be.

The jury thereupon retired and after due deliberation returned into the court with a verdict of guilty, and thereupon the defendant company interposed its motion in arrest of judgment and for a new trial. Thereafter said motions in arrest of judgment and for a new trial having come on to be heard and argued by counsel, the same were, upon due consideration, overruled and refused, as will more fully appear from the following decision by the court (Dickinson, *J.*):

The prosecution in this case began with an information filed under the Food and Drugs Act and the amendment thereto. The first three counts of the indictment are under the original act and charge different acts of misbranding or false and misleading statements respecting the composition of a medicine put out by the defendant under the trade name of "Bad-Em Salz." The fourth count is under the Sherley amendment to the original act, and charges the offense of making false and fraudulent statements as to the curative properties of the salts manufactured by the defendant.

The case was fully and exhaustively tried and defended, resulting, on April 7, 1915, in a verdict of guilty. The motions may be treated as one and are planted upon four propositions: The first is an attack upon the constitutionality of the Sherley amendment. The position is taken that it is beyond the power of Congress to make a crime of the act of a defendant in proclaiming his belief in the curative properties of a medicine. The argument upon which this is based is so fully met by the opinions accompanying the ruling in U. S. *v.* Johnson, 221 U. S., 488, that we do not feel called upon to give it further discussion.

The second ground of complaint is that the defendant has not received the notice required by the fourth section of the Food and Drugs Act. This complaint is disposed of by the case of the United States *v.* Morgan et al., 222 U. S., 274.

The third complaint is that the indictment was found and tried and a conviction thereunder had without other authority for the institution of the prosecution than an information emanating from the office of the United States district attorney without affidavits in support of it appearing. The facts are that an information with supporting affidavits was filed September 3, 1914. This involved two counts. Another information was filed March 17, 1915. This was the basis of the four counts involved in the indictment upon which the defendant was convicted. The information was based upon the affidavits previously on file. No affidavits were physically attached

to the second information. The discussion of the legal consequences flowing from this is for the moment reserved.

The fourth complaint is that the whole trend of the charge was toward conviction in that it kept the attention of the jury faced in the direction of the guilt and not the innocence of defendant. It must be conceded that a reading of the charge affords some ground for this complaint. It is, however, more seeming than real. The circumstances which gave the framing to the charge brought this about. Before the charge was delivered the attention of the court was called to the fact of certain newspaper publications and discussion of the case. The best method of dealing with the situation was made the subject of a conference between counsel and the trial judge. It was not known whether any of the jury had seen the publication referred to. If they had not seen it, a direct reference to it might do more harm than good. It was thought that the condition could be best met by instructing the jury as to the presumption of innocence and bringing before their minds the responsibility resting upon them to find the facts from the evidence in the case and to acquit unless the proofs brought home to them a conviction of defendant's guilt beyond all reasonable doubt. The trial judge complied with the suggestion made and charged the jury at length, and, if anything, at undue length, in emphasizing the defendant's rights of trial. This was done with such fullness at the commencement of the charge that we can not find that the effect of it was lost upon the jury by anything subsequently said, nor that the defendant was prejudiced by the later features of the charge. Over and beyond these specific grounds of complaint lies the broader one that there was no evidence in the case to justify the defendant's conviction of a crime. The situation in this view of it may be voiced in the phrase that the defendant, if punished, will have been punished for the crime of medical heterodoxy and not for any offense against the law. In other words, the president of the defendant company, who is himself a physician, advanced a theory advocated by others as well as by himself for the treatment of cases commonly known as gallstone cases. In opposition are eminent physicians and surgeons, and, as the argument might concede, the weight of scientific medical opinion is against him. Inasmuch, however, as the treatment is the subject of controversy and its efficacy within the domain of opinion, the minority can not be convicted of crime merely because they are outnumbered. It is certainly true that a man should not be convicted of fraud merely because he advocates a theory of medicine which at the time had not received the sanction of the indorsement of the medical profession. It is equally true that a fraud or a faker can not escape the consequences of his fraud by the mere fact that some one may honestly believe in the theory which he fraudulently and dishonestly exploits. The broad distinction between things which are frauds and things which are not frauds is clear. It would be difficult and indeed seems to be impossible to give a definition of such frauds in words. Supposititious cases illustrating the distinction could be multiplied beyond number. The essential difference is a fact, and in the administration of the criminal law is a fact to be found by a jury. As applied to the evidence in this case, the statement is easily credible that a man believes in and honestly advocates a course of taking the waters of certain springs as a specific for the prevention of gallstones in the sense of ameliorating the conditions to which the formation of gallstones are due; it is conceivable that a man may give a like advocacy to the theory that gallstones when once formed may be dissolved, and there may be other persons of like opinions with himself.

The views thus expressed and the treatment advocated may be groundless in fact and unsupported by respectable professional opinion, and yet the holder of them would not be the proper subject of criminal prosecution. By the very same token, however, another man might advocate a remedy and put out a medicine to be purchased by the sufferers from ailments or diseases, real or imaginary, and the act itself be so clearly false and fraudulent that the mind would not hesitate to reach a conviction of his criminal guilt. The fact that there was a widely spread disposition among people to give credence to the statement because of a superstitious belief in its efficacy, or indeed such a reputation for the remedy itself as to make people prejudiced in its favor, would not diminish but would increase the guilt of him who sought to make money by false statements and fraudulent devices. It is difficult, and indeed practically impossible, to draw a line in the abstract other than a broad line between these two things. There would seem to be no other way of dealing with the subject than to submit to the common-sense judgment of a jury to find whether in a given case the acts of a defendant have been honest, however mistaken, or whether they have been false and fraudulent. The present case may well be considered a test case. There is a wide spread belief, whether well or ill founded, in the curative properties of the waters of many of the springs which issue out of the earth. The predisposition to belief in their efficacy may have its foundation in the search for the fountain of youth. Certain words have become polarized with this meaning and

excite a feeling of hope or expectation in the minds of sufferers, particularly those who suffer from certain ailments. The word spa and the word bad are of this kind. The result of the use of such words is very much akin to the thoughts which, from the principle of the association of ideas, are called up by the use of certain widely advertised proprietary words.

In order to determine what basis of merit lies at the bottom of the fame of certain springs the knowledge and skill of the chemist have been called into exercise and the waters have been analyzed and the ingredients which are believed to have contributed chiefly to their efficacy have been determined. It is a short step from this knowledge to the expedient of artificially reproducing the waters or to the more direct method of bottling and transporting the waters themselves or to facilitate the transportation by the process of evaporation and then reproducing a water from the residuum salts. Starting with this widely spread belief in the efficacy of certain natural waters and following this with the thought of reproduction, either in fact or in equivalents, the defendant put on the market the medicine which it widely sells. Indeed, the president of the company in his testimony gave this history of the evolution of the idea of putting these salts upon the market. The idea began with the recommendation of patients suffering from certain ailments to go to Carlsbad or to Ems or to certain other springs and there take the waters. The next development of the idea was that a treatment would be given which is the medicinal equivalent of what could be had at the springs themselves. The standard formula for effervescent artificial Carlsbad salts given in the National Formulary was not believed to be the best combination of salts for the purpose. To vary from this and yet put out the substitute as artificial Carlsbad salts was thought to be inimical to the provisions of the statute. The fully developed thought was to put out another combination of salts believed to be a reproduction and in that sense a representation and in another sense an equivalent of the medicinal properties of the Carlsbad waters. The embodied thought was therefore put into this product under the name of "Bad-Em Salz." This put behind this proprietary medicine the widespread belief of people in the efficacy of these natural spring waters and the thought that they could get the same benefit from a treatment in their own homes which they would receive directly from the Carlsbad or Bad-Ems waters. The further thought was to give the sale of these salts the additional boost of a statement of their curative or therapeutical properties. Had this been fairly done it could not be said that there was involved in it any infraction of any criminal statute.

The charge against this defendant, however, was that the medicine was misbranded in the respect that it was put out under certain false and misleading statements, the essence of which were (was) that the impression was conveyed to the users of the medicine that they were getting the benefit of the very salts which are contained in the natural waters of the springs which had acquired a world-wide fame, and that false and fraudulent statements were made as to the curative effects or results which would flow from the use of this medicine. Right here is the fulcrum on which the lever for the argument on behalf of the defendant is sought to be placed.

As to the misbranding features of the indictment, the defensive position is taken upon the fact that the statements put out by the defendant were neither false nor misleading, and with respect to the curative features, that inasmuch as the results claimed to follow from the use of the medicine was a matter of opinion, there was no basis for a finding of guilt.

The answer made to these propositions by counsel for the United States is the only answer to which they are open and that is that the statement of fact upon which the first proposition turns is one to be determined by a jury. It is not a necessary condition of a finding of guilt that the statement of what the drug is should be a statement flatly and baldly false, but that the word "misleading" in the act has its function, which is to bring the statement within the inhibition of the statute if it is such as to create or lead to a false impression in the mind of the reader as to what the ingredients or the composition of the drug are.

This is the charge made in the first three counts of the indictment, and this is the fact which the jury has found against the defendant.

With respect to the charge under the Sherley amendment, the answer of the United States is that a man who has in fact made false and fraudulent statements as to the curative properties of the drug which he is selling can not when pursued by justice take refuge in the statement that he was expressing his opinion or in being able to find others who honestly believed in the statements made. Here, again, the question of guilt or innocence turns upon the fact and here, again, the fact is one which must be determined by the jury, and here, again, the jury has determined the fact against the defendant. The charge of the court in this feature or aspect of the case was heard by the jury, and therefore must be read in the light of the argument which had been addressed to them. The president of the company, when upon the witness stand,

testified to the honesty of the statements made and to the truth of the claims made for the results of the treatment advocated. This was impressively supported by counsel for the defendant in his argument that the defendant was not to be convicted because the statements made were not believed in by the witnesses called for the United States, and that a defendant could not be convicted because he entertained an opinion, even if that opinion was a mistaken one, and that the fact that the claims made were within the domain of opinion entitled the defendant to a verdict of acquittal.

These propositions were all affirmed by the court, unless the jury had been convinced by the evidence in the case that the statements as to what the drug was were in fact false and misleading and unless the statements of what it would do were both false in fact and were fraudulently made.

The feature of the charge complained of that the illustrations "were all illustrations of guilt and none of innocence" could not have prejudiced the defendant, for the reason that following the course of the argument made by counsel for the defendant they enforced his argument and reinforced his position by impressing upon the jury that there could be no conviction unless the defendant had been guilty of an arrant fraud such as those embodied in the illustrations given.

This brings us back to the only undiscussed complaint now made—that no one can be called upon to defend to a criminal charge which is not based upon reasonable grounds appearing from statements of fact authoritatively made and sanctioned by the oath of some one who has a knowledge of the facts or its legal equivalent in solemnity and responsibility, is a proposition having behind it the highest sanction of the law. The forms of practice in making criminal accusations which have grown out of this are the outer protections which are thrown around every citizen, and there can be no departure from them.

We have not had the opportunity to examine the record in this case with respect to the fulfillment of these conditions preliminary to a trial. We understand the fact to be, however, and it is stated without denial, that the action of counsel for the United States in bringing this prosecution was based upon affidavits made by those having a knowledge of the facts and upon the probable cause which was disclosed by the affidavits. These affidavits are of record. The first information brought home to the defendant charges which would have taken the form of two counts in an indictment. Counsel for the United States subsequently amplified the form of the charges by putting them into the shape of the four counts of the present indictment. The information in the present prosecution was based upon the affidavits which were of record. The complaint now made, as we further understand it, is merely to the feature that the affidavits upon which the information was based are not physically attached to the information itself. We do not think this to afford any legal reason for interfering with the verdict, although we have no wish to lessen the protection thrown around the defendant. U. S. *vs.* Gruver (35 Fed., 58) and U. S. *vs.* Baumert (179 Fed., 735) dispose of this phase of the case.

The motive and policy of the law which lies behind legislation of this general kind is highly promotive of public good. The evils sought to be removed and prevented spring out of conditions requiring tactful and even delicate treatment. Such laws, if arbitrarily enforced, may easily take the form of an unwise dictatorial interference with the pursuits of others. There is a natural temptation to overdo by trenching upon the domain which properly belongs to the ethics of the medical profession. There is danger also that the public will come to rely upon the protection promised by such laws, and therefore relax individual watchfulness. Such laws, therefore, should be administered in such a way as that honest and well-intentioned business may not be hampered, but the detection of frauds and cheats will be made sure and their conviction and punishment rendered certain. The temptation even to those who can not fairly be termed "unscrupulous" is to yield to the suggestions of greed and come as close to the forbidden line as they safely can. The only sure course in the administration of laws of this kind is to leave the determination of guilt or innocence in a given case to the sound judgment of a jury supervised by the wisest scrutiny which the trial judge can give to make sure that no one is convicted without guilt. As has already been stated, this case discloses acts that are not far over the line of what the defendant might lawfully have done. The jury found, however, that it has transgressed that line, and we are not able to convict the jury of having misjudged the real facts in the case.

The motions in arrest of judgment and that for a new trial are therefore both denied.

On April 30, 1915, the court imposed upon the defendant company a fine of $100, in conformity with the foregoing verdict of guilty returned by the jury.

C. F. MARVIN, *Acting Secretary of Agriculture.*

WASHINGTON, D. C., *July 17, 1915.*